IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; JEANNE WALLACE individually as surviving spouse of Joseph Wallace, deceased, AND as Personal Representative of the ESTATE OF JOSEPH WALLACE; JAMES WALLACE; and SAMUEL WALLACE; EDDIE VIERS, individually as surviving spouse of Teresa Viers, deceased, AND as Personal Representative of the ESTATE OF TERESA VIERS Plaintiffs, vs. UNIVERSITY OF IOWA HOSPITALS AND CLINICS, an Iowa Entity; ADEMOLA ABIOSE; COLUMBIA UNIVERSITY MEDICAL CENTER, a New York Entity; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL, an Illinois entity; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE, a Texas entity; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL, an Ohio entity; ROBERT HOPKIN; UNIVERSITY OF MINNESOTA, a Minnesota entity; MICHAEL MAUER; DUKE UNIVERSITY HEALTH CENTER, a North Carolina entity; MANESH PATEL; UNIVERSITY OF WASHINGTON MEDICINE, a Washington entity; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL, a Massachusetts entity; KATHERINE SIMS; UNIVERSITY OF ALABAMA AT BIRMINGHAM MEDICINE, an Alabama entity; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER, a California entity; WILLIAM WILCOX; UNIVERSITY OF VERSAILLES, a French entity; AND DOMINIQUE GERMAIN Defendants.	)	Civil Action No. 22-752 Class Action *Electronically Filed*

COMPLAINT

AND NOW comes the Plaintiffs, by and through their counsel, C. Allen Black, Esquire, and hereby file this Complaint as follows.

1. D.J. ("Plaintiff D.J.") is a male minor with Fabry disease, represented by and through guardians Chastity Johnson, who currently resides in Wise, Virginia and is a citizen of Virginia. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, hypohidrosis, and debilitating fatigue. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. [1,] The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking low dose Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for

[1] "[I]f an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible. (FN)15" *U.S. v Rutherford,* 442 U.S. 544, 556 (1979) [FN13].

treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.[2]

2. Plaintiff Toni Cordova is an adult individual with Fabry disease who currently resides in Reno, Nevada and is a citizen of Nevada. She had not been diagnosed with Fabry until the shortage began in 2009. Relying on the expert recommendations of the Defendants, she was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2011 to 2012. She had never received a full dose of the drug until the Fabrazyme shortage was over. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in her clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, stroke, transischemic attacks presenting as strokes, white matter deposition in the brain (inflammatory foci), neuropathic pain, chronic debilitating fatigue, and chronic gastrointestinal distress including uncontrollable diarrhea. Her disease has increased due to her reasonable reliance on ineffective treatment in lieu of effective treatment. Had she known that the "low dose" was ineffective and dangerous, she would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life

[2] By registering the study with the National Institutes of Health, all researchers and sponsors agree to follow the "Common Rule" for protection of human research subjects established by the Federal Government.

expectancy has been shortened due to taking "low dose" Fabrazyme, and she is now at special risk for developing what the Defendants describe as residual effects of "low dose" because she reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

3. Plaintiff John Cortina is an adult individual with Fabry disease was a resident and citizen of Brewster, New York at the time of receiving contaminated and low-dose Fabrazyme, but now is a citizen of North Carolina. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, acroparesthesias, and cardiovascular hypertension. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or

obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

4. Plaintiff George Demko is an adult individual with Fabry disease who currently resides in Pittsburgh, Pennsylvania, and is a citizen of Pennsylvania. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, neuropathic pain, memory loss, arterial blockage, and chronic debilitating fatigue. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would

have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

5. Plaintiff Mary Helton is an adult individual with Fabry disease who currently resides in Charlestown, Indiana and is a citizen of Indiana. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, she was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in her clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, transischemic attacks presenting as stroke, intracranial hypertension, optic nerve swelling, vision loss, hearing loss, neuropathic pain, multiple Fabry Crises, cardiac arrhythmia,

chronic debilitating fatigue, and progression of kidney disease. Her disease has increased due to her reasonable reliance on ineffective treatment in lieu of effective treatment. Had she known that the "low dose" was ineffective and dangerous, she would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and she is now at special risk for developing what the Defendants describe as residual effects of "low dose" because she reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

6. Plaintiff Donovan Helton is an adult individual with Fabry disease who currently resides in Clinton, Indiana. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, heart

arrhythmia, chronic debilitating fatigue, heat intolerance, transischemic attacks, proteinuria, multiple Fabry crises, and neuropathic pain. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. Plaintiff was a minor at the time of the shortage requiring special ethical considerations for informed consent.

7. Plaintiff Sydney Johnson, also known as Sydney Holmes-Dowdy is an adult with Fabry disease who currently resides in Wise, Virginia and is a citizen of Virginia. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. She was delivered and injected with "low-dose" Fabrazyme from 2009 to 2012. Plaintiff's clinical status has deteriorated as the Fabry disease has accelerated due to the "low dose" Fabrazyme treatment as evidenced by the occurrence, progression, and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to

Fabrazyme, vascular globotriaosylceramide deposition, hypohidrosis, and debilitating fatigue. Her disease has increased due to her reasonable reliance on ineffective treatment in lieu of effective treatment. Had she known that the "low dose" was ineffective and dangerous, she would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and she is now at special risk for developing what the Defendants describe as residual effects of "low dose" because she reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742. Sydney Johnson was a minor at the time of filing her complaint requiring special ethical considerations for informed consent.

8. Plaintiff Damon LaForce is an adult individual with Fabry disease who currently resides in San Pedro, California and is a citizen of California. While a resident and citizen of Virginia, Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low

dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme requiring extensive pre-medication that he did not require prior to receiving the "low dose" of drug, vascular globotriaosylceramide deposition, debilitating fatigue, neuropathy, anaphylactic infusion reactions, and acroparesthesias. "low dose" also caused antibody sensitization to Fabrazyme making it impossible for him to resume full dose treatment with Fabrazyme without requiring steroids as he had before the "low dosing" began. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

9. Plaintiff Michael Masula is an adult individual with Fabry disease who currently resides in Pittsburgh, Pennsylvania and is a citizen of Pennsylvania. Plaintiff was on treatment

with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, transischemic attacks presenting as stroke, neuropathic pain, acroparesthesias, dental erosion and loss of teeth, and chronic gastrointestinal distress including uncontrollable diarrhea. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. The Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

10. Plaintiff James Matthews is an adult individual with Fabry disease who currently resides in Indian Trail, North Carolina and is a citizen of North Carolina. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, end-stage renal disease (stage V) requiring dialysis, kidney transplant, complications of the first kidney transplant leading to dialysis and currently requiring a second kidney transplant, heat intolerance; neuropathy, fatigue, and anhidrosis. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended

and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

11. Plaintiff Thomas Olszewski is an adult individual with Fabry who currently resides in Grayling, Michigan and is a citizen of Michigan. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, chronic obstructive pulmonary disease, heart surgery, multiple heart catheterizations, neuropathic pain, acroparesthesias, and chronic debilitating fatigue. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. Plaintiff's life expectancy has been shortened due to taking "low dose" Fabrazyme, and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose"

Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

12. Plaintiff Tom Stanziano is an adult individual who currently resides in Oldsmar, Florida, and is a citizen of Florida. Plaintiff was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease has increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, anaphylactic infusion reactions, acroparesthesias, hearing loss, depression, insomnia, and progression of renal disease. "low dose" also caused antibody sensitization to Fabrazyme making it impossible for him to resume full dose treatment with Fabrazyme without steroids as he had before the "low dosing" began. His disease has increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. Plaintiff's life expectancy has been shortened due to taking "low

dose" Fabrazyme and he is now at special risk for developing what the Defendants describe as residual effects of "low dose" because he reasonably relied on the Defendants' expertise for taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

13. Plaintiff Eddie Viers is an adult individual who currently resides in Grundy, Virginia and is a resident of Virginia and was the spouse of Teresa Viers. Eddie Viers is the Administrator of the Estate of Teresa Viers, who was on treatment with FDA-approved doses of Fabrazyme prior to June 2009, and died due to the effects of "low-dose" Fabrazyme delivered and administered from 2009 to 2012, as evidenced by: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, recurrent febrile illness, chronic debilitating fatigue, exercise intolerance, heat intolerance, neuropathic pain, recurrent kidney infections, anaphylactic infusion reaction, increased hemoglobin count, increased creatinine, progression of kidney disease, proteinuria, and enlargement of the heart that all contributed to her death in September of 2019. Plaintiff's life expectancy was shortened due to taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew she would be required to take. She is registered in the Fabry Registry database as a

research subject with the clinical outcome of death. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

14. Plaintiff Jeanne Wallace is an adult individual who currently resides in Richmond, Virginia and is a Virginia citizen and was the spouse of Joseph Wallace. Jeanne Wallace is the executor of the Estate of Joseph Wallace, who was on treatment with FDA-approved doses of Fabrazyme prior to June 2009. Relying on the expert recommendations of the Defendants, he was delivered and injected with ineffective and dangerous "low dose" Fabrazyme from 2009 to 2012. Defendants' ongoing concealment of the dangerous nature and the lack of efficacy of the "low dose" resulted in his clinical status deteriorating as the Fabry disease had increased and accelerated due to the "low dose" Fabrazyme treatment, as evidenced by the occurrence and exacerbation of at least the following physical injuries, symptoms, and diagnostic criteria: immunological sensitization to Fabrazyme, vascular globotriaosylceramide deposition, and acroparesthesias that all contributed to his death in 2016. His disease had increased due to his reasonable reliance on ineffective treatment in lieu of effective treatment. Had he known that the "low dose" was ineffective and dangerous, he would have sought an effective dose or obtained alternative medication through the federal government's "compassionate use" program instead of waiting for the shortage to end. Plaintiff's life expectancy was shortened due to taking "low dose" Fabrazyme. Plaintiff was also damaged by paying over $200,000 for medically worthless Fabrazyme. The "low dose" Fabrazyme was medically worthless because it was ineffective for treating Fabry disease and unsafe to administer at the dosage that the Defendants recommended and knew he would be required to take. He is registered in the Fabry Registry database as a research subject with the clinical

outcome of death. ClinicalTrials.gov Identifier: NCT00196742 available at https://clinicaltrials.gov/ct2/show/NCT00196742.

15. Plaintiff James Wallace is an adult individual that resides in Nashville, Tennessee and is a Tennessee citizen and is a surviving son of Joseph Wallace.

16. Plaintiff Samuel Wallace is an adult individual who currently resides in Richmond, Virginia, and is a Virginia citizen and is a surviving son of Joseph Wallace.

17. Defendant University of Iowa Hospitals and Clinics, an entity Defendant, is an Iowa corporation with a principal place of business at 200 Hawkins Drive, Iowa City, IA 52242. It receives federal funding.

18. Defendant Ademola Abiose, M.D., a physician Defendant, resides in Cleveland Ohio and is a citizen of Ohio. He was a citizen of Iowa from 2009 to 2011 and was employed at the University of Iowa Hospitals and Clinics

19. Defendant Columbia University Medical Center, an entity Defendant, is a New York corporation with a principal place of business at 630 West 168th Street, New York, New York 10032. It receives federal funding.

20. Defendant Maryam Banikazemi, M.D., a physician Defendant, is a citizen of New York and was a citizen of New York from 2009 to 2012. She was an employee of Columbia University Medical Center between 2009 and 2012.

21. Defendant Children's Memorial Hospital, an entity Defendant, is an Illinois corporation with a principal place of business at 225 E. Chicago Ave., Chicago, IL 60611. It receives federal funding

22. Defendant Joel Charrow, M.D., a physician Defendant, is a citizen of Illinois.

He has been an employee of Children's Memorial Hospital from at least 2009 to the present.

23. Defendant Baylor College of Medicine, an entity Defendant, is a Texas corporation with a principal place of business at One Baylor Plaza, Houston, TX 77030.

24. Defendant Christine Eng, M.D., a physician Defendant, is a citizen of Texas. She had been an employee of Baylor College of Medicine since at least 2009.

25. Defendant Cincinnati Children's Hospital Medical Center, an entity Defendant, is an Ohio corporation with a principal place of business of 3333 Burnet Ave., Cincinnati, OH, 45229. It receives federal funding.

26. Defendant Robert Hopkin, M.D., a physician Defendant, is a citizen of Ohio. He has been an employee of Cincinnati Children's Hospital since at least 2009.

27. Defendant University of Minnesota Medical Center, an entity Defendant, is a Minnesota Corporation with a principal place of business at 500 Harvard St. SE, Minneapolis, MN, 55455. It receives federal funding.

28. Defendant Michael Mauer, M.D., physician Defendant, is a citizen of Minnesota. He has been an employee of the University of Minnesota Medical Center since at least 2009.

29. Defendant Duke University Health System, an entity Defendant, is a North Carolina Corporation with a principal place of business at 2301 Erwin Road, Durham, NC 27710. It receives federal funding.

30. Defendant Manesh Patel, M.D., a physician Defendant, is a citizen of North Carolina and has been an employee of Duke University Health System since 2009.

31. Defendant University of Washington Medicine, an entity Defendant, is a

Washington corporation with a principal place of business at 325 9th Ave., Seattle, WA 98104. It receives federal funding.

32. Defendant Ronald Scott, M.D., a physician Defendant, is a citizen of Washington. He has been an employee of the University of Washington Medicine since at least 2009.

33. Defendant Massachusetts General Hospital, an entity Defendant, is a Massachusetts corporation with a principal place of business at 55 Fruit St., Boston, MA 02114. It receives federal funding.

34. Defendant Katherine Sims, M.D., a physician Defendant, is a citizen of Massachusetts. She has been employed by Massachusetts General Hospital since at least 2009.

35. Defendant University of Alabama at Birmingham Medicine, and entity Defendant, is an Alabama corporation with a principal place of business of 550 22nd St. South, Birmingham, AL 35223. It receives federal funding.

36. Defendant David Warnock, M.D., a physician Defendant, is a citizen of Alabama. Defendant David Warnock has been an employee of University of Alabama at Birmingham Medicine since at least 2009.

37. Defendant Cedars-Sinai Medical Center, an entity Defendant, is a California corporation with a principal place of business at 8700 Beverley Blvd. Los Angeles, CA 90048. It receives federal funding.

38. Defendant William Wilcox, M.D., Ph.D., a physician Defendant, was a citizen of California from 2009 to 2012. He was employed at Cedars-Sinai Medical Center between 2009-2012.

39. Defendant University of Versailles, an entity Defendant, is a French corporation with a principal place of business of 2 avenue de la source de la Bievre, Montigny, Ile-de-France, France – 78180. The University of Versailles.

40. Defendant Dominique Germain, M.D., Ph.D., a physician Defendant, is a citizen of France and was a citizen of France. He is employed by the University of Versailles and entered the United States to attend the Fabry Stakeholders' Working Group in Chicago, IL, on June 27, 2009.

JURISDICTION AND VENUE

41. Federal jurisdiction is conferred under federal subject matter jurisdiction 28 U.S.C. § 1331 and state law related claims under 28 U.S.C. § 1343; and diversity jurisdiction is also conferred pursuant to 28 U.S.C. § 1332 (a) as defendants and plaintiffs are all from different states and over the Class (as hereinafter defined) pursuant to 28 U.S.C. §§ 1332(d) (2) and (6) of the Class Action Fairness Act of 2005, because one or more members of the Class are citizens of a State different from the Defendant, and the aggregate amount in controversy exceeds two billion one hundred and fifteen million dollars ($2,115,000,000), exclusive of interest and costs.

42. Furthermore, two Plaintiffs are citizens of Pittsburgh Pennsylvania, so as to permit the Western District of Pennsylvania to exercise personal jurisdiction

43. Venue is proper because two Plaintiffs, Michael Masula and George Demko, reside in the Western District of Pennsylvania.

PROCEDURAL BACKGROUND

Some of the facts in this Complaint relate back to factual information in the co-pending product liability action filed by Plaintiffs pending in Massachusetts against Sanofi Genzyme, a pharmaceutical manufacturer. Wilkins *et al*. v. Genzyme (1:21-cv-10023-DPW). No discovery has occurred because the case remains in the pleading stage.

Some facts also relate to another product liability action for wrongful death in Utah. The facts of the Utah case were not known to the Plaintiffs. Specifically, on May 21, 2020, the District Court of Utah granted STAT News' request to unseal Plaintiff's (proposed) Fourth Amended Complaint in the case *Schubert v. Genzyme* (Case 2:12-cv-00587-HCN-DAO). The evidence that was unsealed revealed that "low dosing" Fabry patients with Fabrazyme was both ineffective and dangerous. These specific documents are reference *infra* by the Bates numbered documents that were unsealed (*e.g*., GENZYME [00000]).

Additional facts have been developed herein that show that non-Sanofi Genzyme physicians and state actors have been involved in manipulating data to avoid disclosure of "low dose" effects on American Fabry patients despite recording these data on the Plaintiffs and other American Fabry patients leading to the filing of the current Complaint. The Defendants are not manufacturers or sellers of a drug.

FACTUAL BACKGROUND

Fabry Disease

44. Fabry (pronounced "fah-bray") disease is a rare but lethal heritable genetic illness that occurs in approximately 1 in 3,000 births.

45. Without treatment, the disease results in the premature death of Fabry patients from complications such as renal disease, cardiac disease, and disease of the central nervous system.

46. In Fabry disease, the gene for an enzyme (alpha-galactosidase) required to metabolize a certain fat (globotriaosylceramide, termed "GL-3) is mutated or missing resulting in the buildup of GL-3 in cells, blood vessels, and organs, which causes inflammation and ultimately leads to death, usually from strokes, kidney failure, and/or heart enlargement.

47. While no cure for Fabry disease is yet available, one of the greatest breakthroughs in scientific research on Fabry disease has been enzyme replacement therapy where a synthetic version of the enzyme, Fabrazyme (agalsidase beta), can be infused intravenously every two weeks to effectively treat Fabry patients.

48. Fabrazyme does not reverse damage from Fabry disease but can mitigate the effects of toxic GL-3 production.

49. Fabrazyme infusions temporarily compensate for the absent or mutated agalsidase enzyme by clearing GL-3 buildup from the system.

50. Fabrazyme is rapidly metabolized, so it must be administered every two weeks.

51. In April of 2003, the United State Food and Drug Administration ("FDA") granted rapid orphan drug approval for Sanofi Genzyme Corporation to exclusively market and sell Fabrazyme for the treatment of Fabry patients throughout the United States.

52. Fabrazyme was developed under a federal research grant, so Sanofi Genzyme did not own the patent to Fabrazyme but rather licensed it.

53. The scientific research for the discovery of Fabrazyme was a direct result of U.S.

taxpayer funding.

54. Specifically, the NIH awarded grant no. DK 34045 to Dr. Robert J. Desnick ("Desnick") at the Mount Sinai School of Medicine to develop Fabrazyme as an enzyme replacement therapy to treat Fabry Disease and conduct clinical trials at the Mount Sinai School of Medicine.

55. Mount Sinai was granted U.S. Patent No. 5,356,804 for a method of producing agalsidase beta subject to the requirements and obligations of 35 U.S.C. §§ 200-212, commonly known as the Bayh-Dole Act. Mount Sinai licensed U.S. Patent No. 5,356,804 to manufacture agalsidase beta (Fabrazyme) to Sanofi Genzyme Corporation, which has been the sole FDA-approved supplier enzyme replacement therapy to the U.S. marketplace.

56. Under the Bayh-Dole Act, the U.S. government retained certain rights to the Fabrazyme invention (U.S. Patent No. 5,356,804) to protect the public while Mount School of Medicine owned the title.

57. Fabrazyme was also granted orphan drug status, so Sanofi Genzyme (previously Genzyme Corporation) had a drug monopoly in the United States. Orphan Drug Act, 21 U.S.C. § 360aa *et seq*. "Protection for drugs for rare diseases or conditions"

58. Fabrazyme is the only FDA-approved drug for treating Fabry disease in the U.S., although a competitor drug (Replagal) is available in Europe.

59. From 2009 to 2012, Replagal was available through FDA's "Compassionate Use" expanded access program.

60. Currently, Fabrazyme treatment generally costs over $600,000 per year per patient, and there are over 2,000 Americans diagnosed with the disease.

Fabrazyme Shortage

61. Fabrazyme is produced in bioreactors that are similar to fermentation tanks.

62. Genetically engineered Chinese hamster ovary cells ("CHO cells") secrete the human agalsidase enzyme into the cell growth medium where it is collected and purified into an injectable form.

63. Sometime before June 2009, Sanofi Genzyme Corporation contaminated its bioreactors with Vesivirus 2117 (Allston), a genus of calicivirus.[3]

64. In mid-June 2009, Sanofi Genzyme suspended production of Fabrazyme and several other enzyme replacement drugs manufactured at its plant due to the viral contamination in the bioreactors.

65. In mid-November 2009, Sanofi Genzyme shut the plant down again due to ongoing manufacturing deficiencies.

66. As a consequence, Sanofi Genzyme did not have enough drug to ensure a continued supply to all of its customers both in the United States and overseas.

67. Sanofi Genzyme was also worried about competition overseas, where Replagal was available, unlike in the United States.

68. By 2008, knowing that supplies of Fabrazyme were tenuous, Sanofi Genzyme had conducted work on a Fabrazyme Global Contingency Plan and outlined a proposed response to a supply interruption in a document ("Contingency Plan"). GENZYME638592 (*Schubert*).

[3] Qui Y., et al. "Identification and quantitation of Vesivirus 2117 particles in bioreactor fluids from infected Chinese hamster ovary cell cultures." *Biotechnol Bioeng.* 2013 May;110(5):13042.

69. In the Contingency Plan, Sanofi Genzyme acknowledged that Fabrazyme was "very vulnerable" to manufacturing supply interruptions. The Contingency Plan detailed how Sanofi Genzyme intended to respond to a Fabrazyme supply disruption. *Id*.

70. The Contingency Plan further stated that, in the event of a supply interruption, "strong messaging" would be needed to influence physicians and patients to follow Sanofi Genzyme's suggested allocation plan during the period of shortage. *Id*.

71. Sanofi Genzyme's Contingency Plan states that in the event of a supply interruption, during the initial stages of any interruption, the **"EU markets" would be "protected" with favored treatment** because of what the authors termed the **"business value"** of the European market. *Id.*

72. Under the Contingency Plan, patients in Europe would not, at the outset, be asked to make the same sacrifices in altering their treatment regimen as would U.S. patients. *Id.*

73. In other words, Sanofi Genzyme's 2008 Contingency Plan revealed its deliberate intent to give preferential treatment to European patients in the event of a supply interruption.

74. Sanofi Genzyme planned to give "protection" to the European market during the initial stages of a shortage because Sanofi Genzyme knew that patients in Europe could easily switch to Replagal® while patients in the U.S. could not.

Reduced Dosage of Fabrazyme[4]

[4] For the purpose of the complaint, a "dose" refers to the mass amount of Fabrazyme administered to a patient in one infusion (e.g., 70mg to a 150lb patient), but "dosage" refers to the amount given the patient over time 1mg/kg every two weeks. The pharmacology of Fabrazyme dosage changes whether the correct amount is given according to the patient's weight (1mg/kg) as well as according to how often the drug is administered (every two weeks).

75. In 2009, limited stocks of Fabrazyme were available for supply, all of which were contaminated, so Sanofi Genzyme Corporation recommended a new and untested method of treating Fabrazyme patients with what Sanofi Genzyme called "low dose" Fabrazyme or "dose skipping."

76. "Low dosing" Fabrazyme consisted of Sanofi Genzyme selling a "full dose" in the sense it was the proper mass and number of vials per weight of the patient, but "low dose" in that it was shipped once every 1-6 months instead of bi-weekly as prescribed.[5]

77. Patients were given a choice of taking a reduced dose (0.5-0.2mg/kg) every two weeks or taking a full dose (1mg/kg) administered every month or longer by skipping doses.

78. Either way, the FDA only approved Fabrazyme to be infused intravenously at 1mg/kg every other week, administered as described on the label and prescribed by the Plaintiffs' physicians.

Dose Reduction Recommendations of Fabry Stakeholders Working Group (FSWG)

79. To implement "low dosing," Sanofi Genzyme convened a group of experts and two Fabry patient support groups to implement " low dosing.

80. The organization was termed "The Fabry Stakeholder's Working Group," abbreviated "FSWG."

81. The Fabry Stakeholder's Working Group comprised the physician Defendants

[5] "Low dose" means both dose-skipping and reducing the dose below 1mg/kg or a combination of the two.

who were representing their respective medical institutions according to the FSWG documents.[6]

82. The Fabry Stakeholder's Working Group met twice.

83. The first meeting was held on June 7, 2009, in Chicago, which resulted in a document termed "**Guidance to the Fabry Community on the Management Fabrazyme (agalsidase beta) Supply**. *Temporary Conservation of the Fabrazyme Supply to Minimize the Impact of the Shortage on the Health of Patients*" that was sent to all Fabry patients in the U.S. including all of the named Plaintiffs. Exhibit A.

84. The express stated purpose of the FSWG was to "minimize the risks" to patients and "minimize the impact" of the shortage for all Fabry patients. *Id.* at 2.

85. The second meeting was held on September 23, 2009, where all of the same individuals attended, except Dr. Dominique Germain, a French citizen.

86. In a continuing course of conduct, a second meeting was held that resulted in a document termed "**Revised Guidance to the Fabry Community on the Management of Fabrazyme (agalsidase beta) Supply**. *Temporary Conservation of Fabrazyme Supply for 2009*" that was also sent to all Fabry patients in the U.S. including the named Plaintiffs. Exhibit B.

87. On the cover page of both FSWG documents, it is noted that "individuals or their

[6] The signatories include Defendants Dr. Ademola Abiose (University of Iowa Hospitals); Dr. Maryam Banikazemi (Columbia University Medical Center); Dr. Joel Charrow (Children's Memorial Hospital); Dr. Christine Eng (Baylor College of Medicine); Dr. Robert Hopkin (Cincinnati Children's Hospital Medical Center; Dr. Michael Mauer (University of Minnesota); Dr. Manesh Patel (Duke University Health Center); Dr. Ronald Scott (University of Washington); Dr. Katherine Sims (Massachusetts General Hospital); Dr. David Warnock, (University. of Alabama at Birmingham Medicine); Dr. William Wilcox (Cedars-Sinai Medical Center) and Dr. Dominque Germain (University. of Versailles), all of which received payments from Sanofi Genzyme.

institutions or organizations receive or have received funding from Sanofi Genzyme."; however, no specific information is revealed as to any particular physician Defendant or entity Defendant that received these funds. *See* Exhibits A and B.

88. In the June 2009 FSWG letter, the Defendants recommended half-dosing Fabrazyme instead of full doses.

89. In the second FSWG letter in September 2009, the dose reduction was further decreased to one-third, even including a dose reduction table for doctors and patients to follow.

90. The letters couched the recommendations as voluntary, stating that the decisions were ultimately up to the treating physician. Still, the Defendants knew that the dose reductions would be mandatory because Sanofi Genzyme would adopt the FSWG recommended dose reductions when shipping Fabrazyme irrespective of the physician-patient treatment decision.

91. The dose reduction from the "temporary shortage" lasted an additional two and one-half years until the spring of 2012.

92. The FSWG did not meet again, although all the physician Defendants treated their own Fabry patients during the shortage by administering "low doses" to them and collected data on the effects of the "low dose" for research on the medical effects of "low dose" Fabrazyme.

Unethical Research on "Low Dose" Patients by the Defendants

93. In the second FSWG letter to U.S. Fabry patients, the physician Defendants also encouraged all U.S. doctors and patients to document the effects of "low dosing" in a U.S. database termed "The Fabry Registry."

94. Most U.S. Fabry patients, including the Plaintiffs, are registry research subjects.

95. The Fabry Registry is ostensibly an "observational" longitudinal study for collecting data on Fabry disease and treatment where "[n]o experimental intervention is involved," even though the protocol was changed so that all U.S. research subjects were mandated to receive an experimental "low dose" of Fabrazyme. (NIH ClinicalTrials.gov Identifier: NCT00196742)[7]

96. Unlike the original use of the Fabry Registry, the FSWG stated in 2009 that it specifically wanted to collect data on U.S. patients being "low dosed" "[B]ecause there is limited published data on the clinical effects of dose reductions or treatment interruptions, the collective data from many patients may provide valuable answers to these important unanswered questions through future analyses." Exhibit B, p.5.

97. Unilaterally lowering the dose of Fabrazyme while collecting data on the unknown effects is substantive human experimentation despite the description of the Fabry Registry being observational because patients were required to take it or receive nothing at all.

98. Under 21 CFR § 312.3 (b), treating Fabry with "low dose" Fabrazyme is considered an investigational use for a new drug because the drug is only known to be efficacious at 1mg/kg every other week. "The FDA has long held that when an investigator limits his choices, his patient's choices and the choices of the people working for him in the treatment of those patients, then he is conducting a clinical investigation. That is different from the practice of medicine, where the primary intent is to treat the individual patient. (*emphasis added*) Center

[7] Available at https://clinicaltrials.gov/ct2/show/NCT00196742

for Drug Evaluation and Research, FDA, "Warning Letter to Hennepin County Medical Center" June 2021).[8] *See also* FDA's guidance to industry Investigational New Drug Applications (INDs)- Determining Whether Human Research Studies Can Be Conducted Without an IND (published in September 2013), at 4, 15 ("For example, a randomized trial evaluating an unapproved use of a lawfully marketed drug is a clinical investigation and may require an IND).

99. None of the Plaintiffs were under the treatment or care of Defendants, so the Defendants had no personal knowledge of the particular risks and adverse effects that "low dose" would have on individual patients other than the data the Defendants have collected on them through the Fabry Registry.

100. The Defendants did not obtain informed consent from any of the U.S. patients because the change of the protocol from observational status to monitoring the clinical effects of the unapproved dosages of Fabrazyme was not put before an Institutional Review Board. There could not be any yearly follow-up as required under the Common Rule promulgated in response to the Belmont Report for the protection of human research subjects.[9]

101. The Defendants did not obtain informed consent from patients because they did not tell research subjects what the effects of "low dose" Fabrazyme were likely to be.

102. The Defendants did not obtain informed consent from patients because they did tell the research subjects that the emerging data in the Fabry Registry likely showed that "low dose" was ineffective and dangerous.

[8] Available at https://www.hennepinhealthcare.org/wp-content/uploads/2021/10/FDA-Warning-Letter-and-Hennepin-Healthcare-response-letter-Hospital-MayJune-2021.pdf

[9] *See,* for example the Office of Human Research Protection and the Common Rule available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

103. The Defendants also did not obtain informed consent because American Fabry patients were not allowed to voluntarily opt out of "low dose" and return to the FDA approved dose of Fabrazyme that was (and remains) the gold standard of medical care for treating Fabry disease in the U.S. thereby removing any autonomy and the ability to determine their own medical care.

104. The Defendants did obtain informed consent because the FSWG did not disclose that American Fabry patients would be treated unequally. The Europeans could obtain and did obtain a full dose of Fabrazyme during the shortage.

105. The Defendants also did not obtain informed consent even within the United States because some high prestige Americans were given full doses, but the unequal treatment was not disclosed to any of the other Fabry registry patients.

106. The Defendants also did not obtain informed consent because the FSWG members limited disclosing their conflicts of interests to an ambiguous aggregate, stating that "some" of them had received money from Sanofi Genzyme, when in actuality "most" of them, if not all, had been paid by Sanofi Genzyme.

107. The Defendants also did not obtain informed consent because the FSWG members limited disclosure to the Lubanda study and not the more clinically relevant Vedder study discussed *infra* that showed "low dose" was ineffective. [10,11]

[10] Vedder AC, Breunig F, Donker-Koopman WE, Mills K, Young E, Winchester B, Ten Berge IJ, Groener JE, Aerts JM, Wanner C, Hollak CE: Treatment of Fabry disease withdifferent dosing regimens of agalsidase: effects on antibody formation and GL-3. Mol Gen Metab. 2008

[11] Lubanda JC, Anijalg E, Bzdúch V, Thurberg BL, Bénichou B, Tylki-Szymanska A. Evaluation of a low dose, after a standard therapeutic dose, of agalsidase beta during enzyme replacement therapy in patients with Fabry disease. Genet Med2009;11(4):256

108. The Defendants acted unlawfully because they did not attempt to warn patients that the "low doses" were likely ineffective and dangerous once this data became evident either through the data being collected in the registry or through observation of the effects of "low dose" on their own patients as is required during any use of an investigational new drug whether an Investigational New Drug application has been submitted.

109. The FSWG was also coercive.

110. It acted in unison to "persuade" Americans to take "low doses, "without discussing whether individually discussing the decision in private with individual Fabry patients. The group of doctors making the recommendation was viewed by the Plaintiffs as more persuasive than if the members published their opinions separately.

111. It did not include a contact number for an Institutional Review Board but instead directed individuals to the manufacturer of the drug.

112. The members of the FSWG used guilt and shame to encourage compliance. By describing the shortage as affecting everyone, the implicit understanding was that not being a team player would result in injury to other innocent victims or shaming within the Fabry community. This threat is especially magnified because Fabry patients are often related to each other and treated by the same physician. If one family member found out another was receiving a full dose, acrimony and retaliation would result.

113. The FSWG was also coercive because the implicit understanding was that if a patient did not take the "low dose, " they would get nothing. In other words, "something was better than nothing.

114. If the "low dose" was rejected, then dissenters would be punished by not

receiving anything, while the compliant group would at least get something.

115. The Defendant Institutions all require informed consent for all research studies conducted by employees and actively monitor their employees for breaches of the "Common Rule" protecting human research subjects no matter the source of funding.

116. The research conducted by the Defendants was on a taxpayer-funded patented drug in which the U.S. government held rights and responsibilities toward U.S. Fabry patients.

117. The Defendant institutions are required to investigate and report research misconduct to the Office of Research Integrity.

118. The Defendants are aware of the ethical and legal responsibilities for conducting human clinical trials since they have conducted and continue to conduct human research and have received federal funding to conduct clinical trials on humans with other conditions.

Plaintiffs' Discovery That "Low Dosing" is Useless and Dangerous

119. The perception among the Plaintiffs has been that "something was still better than nothing" when using "low dose" Fabrazyme, which is what the FSWG wanted individuals to believe.

120. However, The Plaintiffs discovered that something was no better than nothing by May 21, 2020.

121. On this date, the court in Utah unsealed a complaint that held evidence that Sanofi Genzyme knew the "low dose" was ineffective in treating Fabry Disease. *Schubert v. Genzyme* (Case 2:12-cv-00587-HCN-DAO).

122. On March 12, 2012, Dr. Schubert's widow sued Sanofi Genzyme corporation and

other entities for the wrongful death of her husband, who suffered from Fabry.

123. Dr. Schubert was quickly deteriorating on "low dose" Fabrazyme and begged Sanofi Genzyme to give him full doses, but Sanofi Genzyme refused, and Dr. Schubert died of complications from Fabry disease on March 6, 2010.

124. The *Schubert* case settled for an undisclosed amount.

125. Sanofi Genzyme's Global Medical Director, Dr. Daniel Gruskin, who attended both FSWG meetings, colorfully characterized the Lubanda data on which the efficacy of "low dose" was predicated. On January 18, 2011, in an email to his colleague, Andre Richer, Dr. Gruskin said that "We totally screwed the pooch and PV [pharmacovigilance] is to blame, although we let them do it. We sent the EMA [European Medical Association] bullshit data [on "low dose"] and then are surprised when they come up with recommendations to switch to Replagal®." GENZYME511440 (*Schubert*).

126. This same "bullshit data" was presented to the physicians attending the Fabry Stakeholder's Working Group.

127. Specifically, before the shortage, there were only two peer-reviewed and published patient studies studying the effect of Fabrazyme treatment at doses lower than the full FDA-approved dose. One article's principal author was Vedder, and the other's was Lubanda.

128. The Vedder study, which was published in 2007, was the only study evaluating the clinical outcomes of patients on reduced doses. The Vedder study revealed that a lower dose of Fabrazyme (0.2 mg/kg administered every other week) was not clinically efficacious for a large number of subjects enrolled in the study and that "no reduction in left ventricular mass or other disease parameters" was observed after nearly two years of treatment on the reduced dose.

The Vedder study also showed that when study subjects who deteriorated on the reduced dose were switched back to the full FDA-approved dose later, it failed to stop "further progression of the disease."

129. On the other hand, the Lubanda study (cited in the second FSWG letter absent the Vedder study), published in 2009, only evaluated the effect of a lower dosage of Fabrazyme (0.3 mg/kg every 2 weeks) on measurable biomarkers that can be evaluated by lab testing of subjects. The study found that some patients taking the reduced dose had a change in biomarker levels, and some did not.

130. Of critical import, the studied biomarker had not then, and still has not, been proven to be correlated with clinical outcomes. In other words, there is no proof that Fabrazyme in such “low doses” forestalls or delays the progression of cardiac or other disease processes caused by the enzyme deficiency in Fabry Disease patients.

131. Additionally, the authors of the Lubanda study expressly stated in the published study paper that "the small sample size together with the short duration of this exploratory study did not permit analyses of clinical outcomes."

132. To encourage adoption of “low dose, “Sanofi Genzyme touted the Lubanda study, while downplaying the more clinically relevant Vedder study, while simultaneously lying about the projected duration of the shortage.

133. Sanofi Genzyme admitted lying at the FSWG meetings.

134. Dr. Gruskin, then Sanofi Genzyme's Global Medical Director, who had attended both FSWG meetings, sent an email to another Sanofi Genzyme employee who attended the meeting, asking, "Did we lie to the fswg?" The email response from his colleague, John King,

Marketing Director of Fabrazyme, stated, "We are the only ones who didn't" lie. GENZYME047527 (*Schubert*).

135. In October 2009, and while Sanofi Genzyme was implementing and communicating its plan to supply all U.S. patients with "low dose" Fabrazyme without disclosing any medical risks for patients taking the reduced dose, Sanofi Genzyme was actively marketing against Australian governmental approval of a similarly reduced dose of Fabrazyme. Sanofi Genzyme warned the Australian medical authority of grave dangers to patients if the reduced dose was approved for clinical use.

136. From July – to October 2009, the Australian medical regulatory authority was evaluating whether it could reduce the approved dose of Fabrazyme to 0.2 mg/kg every two weeks as the FSWG regulatory body had done to save its citizens 80% of the enormous cost of treatment of Fabrazyme.

137. The Australian medical authority asked Sanofi Genzyme to respond as to whether it was medically safe for patients to order Fabrazyme in a reduced dose.

138. In responding to Australia's recommendation that Fabrazyme be approved at a dose of 0.2 mg/kg administered every two weeks, Sanofi Genzyme's senior management, including many of the same Sanofi Genzyme management involved in reviewing, approving, and communicating the "low-dose" plan for U.S. Fabry patients to accept a reduced dose.

139. Sanofi Genzyme's response to Australian medical authorities warned that reducing the dose "to 0.2 mg/kg . . . across the board would have significant clinical consequences for patients, with the expectation that many would suffer irreversible harm as a result of insufficient dosing," and that "treatment at a higher dose is necessary and may be life-

saving." In the same communication, Sanofi Genzyme stated that the suggestion to "reduce the dose of Fabrazyme® to 0.2 mg/kg in all patients ignores the cumulative evidence in the extant literature" and that to believe such a reduction could occur "with little or no loss of efficacy is conjectural." GENZYME013854; GENZYME013847 (*Schubert*).

140. In the same response letter, Sanofi Genzyme officials cited the Vedder study and its conclusion that a dose of 0.2 mg/kg of Fabrazyme® was "suboptimal" and would not "elicit[] a clinically relevant response to treatment." *Id.*

141. In a related email, Sanofi Genzyme senior management stated that such a "**blanket dose adjustment would be insane.**" GENZYME013840 (*Schubert*).

Specific Knowledge of Defendants

142. The Defendants knew the Fabry Registry data proved that "low dose" Fabrazyme was ineffective and dangerous.

143. Despite Sanofi Genzyme lying to the Defendants, the Defendants still undertook a duty to independently monitor the effects of the "low dose" plan they had implemented and had the means and expertise to monitor the effects through the Fabry Registry.

144. The Defendants specifically stated that the data the Defendants recorded on "low dose" patients would be valuable because there was little data showing that it was efficacious or safe. Exhibit B, p. 5.

145. The Defendants affirmatively stepped outside their role as individual treating physicians to assume responsibility for managing the entire U.S. Fabrazyme supply by creating the autonomous FSWG and representing themselves individually "as internationally-recognized

physicians with deep clinical and scientific expertise" from well-respected institutions who would "minimize the risk for patients." Exhibit A, p.2.

146. Management of the national drug supply to protect citizens during a shortage is the customary government role of state and federal public health authorities.

147. The FSWG recommendations were not recommendations but rather a mandate with the force of law so that American patients could not receive full doses and could not appeal the decision to accept "low doses" to any governmental body. They could only beg Sanofi Genzyme to provide the standard of care their doctors prescribed. The Defendants knew the "low dose" would be made (and had been made) mandatory, thereby defeating any doctor-patient autonomy that existed before the FSWG.

148. The Defendants acted outside of the doctor-patient relationship. Therefore, they were not "practicing medicine" when they appointed themselves governmental public health authorities to manage the allocation of the Fabrazyme supply in all 50 U.S. states without taking into account individual medical conditions.

149. For example, most males are likely to die of Fabry disease by 50, whereas females can live to an average age.

150. The vast majority of U.S. Fabry patients were not under the medical care of any of the Defendant physicians when they mandated that American Fabry patients take the lower dose while collecting data on them without informed consent or the ability to opt-out of the experimental treatment.

151. The Plaintiffs and all American Fabry patients reasonably relied on the FSWG physicians to "minimize the risk to patients" and would not have taken "low dose" Fabrazyme

had they known that "blanket dose adjustment **would be insane**" and that the "low dose" protocol was based on "bullshit data."

152. The ongoing concealment of the registry data on "low dose" treatment made it impossible to discover these material facts of their injuries or the cause of their injuries because the Plaintiffs do not have access to the Fabry Registry or the expertise necessary to analyze the results.

153. The reason that a reasonable person would be "**insane**" to take a lowered dose is that the medical data on "low dose" is "bullshit," as confirmed by the data that was collected on over 1,500 American Fabry patients for two and one-half years.

154. The physician Defendants have always been able to access the Fabry Registry data at their convenience when they encouraged the collection of data on patients receiving "low dose." Physician Defendants have personally accessed these data and continue to access these data to this day.

155. Indeed, between 2009 and at least 2012, all physician Defendants also served on the North American Board of Advisors for the Fabry Registry separately from the Fabry Stakeholders Working Group. Defendant Dominique Germain served on the International Fabry Registry during this period.

156. In 2011, Defendant Dr. David Warnock (Chair) stated in the Foreword to the Fabry Registry Annual Report that "we would like to recognize the many challenges that Fabry physicians and their patients have faced during the past year due to the interruption in the manufacturing of agalsidase beta. Amidst this difficulty, we would like to thank all of the participating sites who have reported their patients' changes in treatment status and other clinical

data during this difficult period."

157. Defendant Dr. Warnock, who chaired the Registry Board, further states that "It is essential that the Fabry Registry collects these data to better understand clinical impact of these treatment changes for patients."

158. Neither Defendant Dr. Warnock nor the other Fabry Stakeholder Working Group physicians have reported this "essential" data and have systematically acted to conceal these data from the Fabry research subjects.

159. The Defendants have not reported this data because it proves the "low dose" of Fabrazyme is ineffective and dangerous compared to the full dose.

160. The Defendants could have disclaimed their recommendation for dose reduction at any point in the two and one-half years of the shortage. Still, after reviewing the data in the Registry the Defendants they did not want to incriminate themselves in the injury of thousands of innocent Americans and the fraudulent billing of hundreds of millions of dollars for "low dose" Fabrazyme to Medicare, Medicaid, Veterans Affairs, and private insurers, none of which pay for experimental, non-FDA dosages of medication.

161. Defendants could have told U.S. Fabry patients that the use of Replagal would have been a better alternative than low-dose Fabrazyme since it had been clinically evaluated and approved for use by many governments' medical regulatory agencies while "low-dose" Fabrazyme had not.[12]

[12] Expanded access (also termed "Compassionate Use") may be appropriate when all the following apply:

1) Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
2) There is no comparable or satisfactory alternative therapy to diagnose,

162. Remarkably, when the European physicians eventually published data on a handful of overseas patients that chose to remain on "low dose," Defendants Dr. Warnock and Dr. Mauer published an article summarizing these European results. It was entitled Fabry *Disease: Dose Matters* but omits discussing the data they had collected over the years in the United States on thousands of Americans who had received "low dose."

163. Instead of discussing the data they held on U.S. Fabry patients, the authors bizarrely ask "What lessons were learned from the 2.5 year shortage of agalsidase beta?" The authors rhetorically reply that "Studies… which took advantage of an unfortunate and quite prolonged drug shortage are important." Id. This muted statement is far from his pronouncement as chair of the Fabry Registry that "It is essential that the Fabry Registry collects these data…." *Emphasis added*.

164. Defendants Dr. Warnock and Dr. Mauer also failed to note that the U.S. Fabry Registry contains data on 1,510 U.S. patients as of 2010 who received "low dose" Fabrazyme, as opposed to the handful of Europeans that received "low doses" and who were the subject of the article.

165. Over 10 percent of the Registry subjects were children in 2010 who required special considerations instead of being aggregated with adult Fabry patients to receive "low

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monitor, or treat the disease or condition.
3) Patient enrollment in a clinical trial is not possible.
4) Potential patient benefit justifies the potential risks of treatment.
5) Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

(Investigational New Drug Application, Subpart I–Expanded Access to Investigational Drugs for Treatment Use. (Food and Drugs, 21 C.F.R. §312.300–312.320 (2009))

doses."

166. The adverse effects of "low dose" are most detrimental to children because as children grow, they need significantly more Fabrazyme as their body mass increases.[13] ("Start of treatment with effective doses of enzyme replacement before age 16, in male Fabry Disease patients is associated with reduced occurrence of renal and cardiac manifestations of Fabry Disease, as assessed by intermediate endpoints.") *Id.* and Tøndel C, *et al.* (concluding that "long-term enzyme replacement therapy in young patients can result in complete globotriaocylceramide clearance of mesangial and glomerular endothelial cells across all dosage regimens, and clearance of podocyte inclusions is dose-dependent." *Emphasis added*.)[14]

167. The blanket dose adjustment recommended by the FSWG did not take children's rapid growth into account. Moreover, many adult Fabry patients who had milder symptoms offered their doses to their children so they would not be injured, but these offers were refused, as was in the case of Plaintiff D.J.'s mother trying to help her son.

168. As published by the Defendants, males are the most likely to benefit from an early start to an effective full dose of Fabrazyme, and, by inference, the most likely to suffer

[13] van der Veen SJ et al. *Early start of enzyme replacement therapy in pediatric male patients with classical Fabry disease is associated with attenuated disease progression*. Mol Genet Metab. 2022 Feb;135(2):163-169. doi: 10.1016/j.ymgme.2021.12.004. Epub 2021 Dec 17

[14] Tøndel C, *et al. Agalsidase benefits renal histology in young patients with Fabry disease.* J Am Soc Nephrol. 2013 Jan;24(1):137-48

from "low doses."[15,16,17, 18,]

169. Even more disturbing, Defendants Dr. Warnock and Dr. Mauer also warned that "low dose" patients, including the children, are at risk for "residual effects" from "low dose" that have never been disclosed.

170. One residual effect is that the "low dose" sensitizes the immune system by creating antibodies so that a patient will not be able to tolerate a return to full dose without medical intervention such as steroid pre-treatment.

171. Another effect is that the "low dose" actually accelerated the course of Fabry disease in some patients as reported by the European Medicines Association, the European equivalent to the FDA.

Defendants' Ongoing Statistical Manipulations to Conceal Data That "Low Dose" is Ineffective

172. The Defendants had hoped that "low dose" Fabrazyme would be effective, but

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[15] **Hopkin RJ**, Cabrera G, **Charrow J**, Lemay R, Martins AM, **Mauer M**, Ortiz A, **Patel MR**, **Sims K**, Waldek S, **Warnock DG**, **Wilcox WR**. *Risk factors for severe clinical events in male and female patients with Fabry disease treated with agalsidase beta enzyme replacement therapy: Data from the Fabry Registry*. Mol Genet Metab. 2016 Sep;119(1-2):151-9. doi: 10.1016/j.ymgme.2016.06.007. Epub 2016 Jun 13.

[16] Ortiz A, **Abiose A**, Bichet DG, Cabrera G, **Charrow J**, **Germain DP**, **Hopkin RJ**, Jovanovic A, Linhart A, Maruti SS, **Mauer M**, Oliveira JP, **Patel MR**, Politei J, Waldek S, Wanner C, Yoo HW, **Warnock DG**. *Time to treatment benefit for adult patients with Fabry disease receiving agalsidase β: data from the Fabry Registry*. J Med Genet. 2016 Jul;53(7):495-502. doi: 10.1136/jmedgenet-2015-103486. Epub 2016 Mar 18.

[17] **Warnock DG**, Ortiz A, **Mauer M**, Linthorst GE, Oliveira JP, Serra AL, Maródi L, Mignani R, Vujkovac B, Beitner-Johnson D, Lemay R, Cole JA, Svarstad E, Waldek S, **Germain DP**, Wanner C; *Fabry Registry. Renal outcomes of agalsidase beta treatment for Fabry disease: role of proteinuria and timing of treatment initiation. Nephrol Dial Transplant.* 2012 Mar;27(3):1042-9. doi: 10.1093/ndt/gfr420. Epub 2011 Jul 29.

[18] **Germain DP**, Weidemann F, **Abiose A**, **Patel MR**, Cizmarik M, Cole JA, Beitner-Johnson D, Benistan K, Cabrera G, **Charrow J**, Kantola I, Linhart A, Nicholls K, Niemann M, **Scott CR**, **Sims K**, Waldek S, **Warnock DG**, Strotmann J; *Fabry Registry. Analysis of left ventricular mass in untreated men and in men treated with agalsidase-β: data from the Fabry Registry.* Genet Med. 2013 Dec;15(12):958-65.

once it became apparent that U.S. Fabry patients were being injured and dying from "low dose," they became publicly silent on the "low dose" issue.

173. Even worse, the Defendants began concealing the "low dose" data they had collected from 2009-2012 in the Fabry Registry.

174. When reporting data from the Fabry Registry after 2012, the Defendants have used methods of statistical manipulation to conceal the American "low dose" data: exclusion and averaging.

175. All the data points are relevant and necessarily reported in any scientifically sound longitudinal study, but when an intervening variable changes (such as dosage), the data is explained, not excluded. Specifically, in a standard longitudinal study, a rise in Fabry-related deaths or adverse events between 2009 and 2012 would be noted due to receiving the "low dose" instead of being excluded altogether.

176. The first paper, published in March 2016, is ambiguous about "low dose" inclusion criteria. It was entitled: *Time to treatment benefit for adult patients with Fabry disease receiving agalsidase β: data from the Fabry Registry*. [19] The materials and methods section states that to be included in the analysis, the patients need to have received a dosage "at or near [*sic*] the recommended dose of 1mg/kg every two weeks." The authors do not explain what criteria constitute a "nearly" recommended dose of Fabrazyme or whether "low dose" patients'

[19] Ortiz A, **Abiose A**, Bichet DG, Cabrera G, **Charrow J**, **Germain DP**, **Hopkin RJ**, Jovanovic A, Linhart A, Maruti SS, **Mauer M**, Oliveira JP, **Patel MR**, Politei J, Waldek S, Wanner C, Yoo HW, **Warnock DG**., *Time to treatment benefit for adult patients with Fabry disease receiving agalsidase β: data from the Fabry Registry*. J Med Genet. 2016 Jul;53(7):495-502. doi: 10.1136/jmedgenet-2015-103486. Epub 2016 Mar 18.

data was reported.

177. The second paper, published in June 2016 the same year, unequivocally excludes the effect of "low dose" data instead of examining the outcomes that Defendant Dr. Warnock had previously stated were essential.

178. The second paper is flawed because it artificially limits the end of the research to when "low dose" began. It was entitled: *Risk factors for severe clinical events in male and female patients with Fabry disease treated with agalsidase beta enzyme replacement therapy: Data from the Fabry Registry*.[20] The materials and methods section states that data were only analyzed up until June 25, 2009, "when many began temporary agalsidase beta dose reductions owning to manufacturing issues."

179. By 2018, Defendants began to hint that blanket dose adjustment was not as efficacious as they had once believed. Defendants Dr. Germain, Dr. Mauer, Dr. Eng, and Dr. Hopkin stated in another review of the data on the handful of Europeans who did not switch to alternative treatment or full doses that "[i]t has become increasingly clear that comprehensive and timely treatment of adult patients with Fabry disease should be directed toward prevention of (further) progression to irreversible tissue damage and organ failure."[21] These Defendants further stated that "[t]he clinical heterogeneity of Fabry disease mandates an individualized

[20] **Hopkin RJ**, Cabrera G, **Charrow J**, Lemay R, Martins AM**,** Mauer M, Ortiz A, **Patel MR**, **Sims K**, Waldek S, Warnock DG, **Wilcox WR**. *Risk factors for severe clinical events in male and female patients with Fabry disease treated with agalsidase beta enzyme replacement therapy: Data from the Fabry Registry.* Mol Genet Metab. 2016 Sep;119(1-2):151-9. doi: 10.1016/j.ymgme.2016.06.007. Epub 2016 Jun 13.

[21] Ortiz A, **Germain DP**, Desnick RJ, Politei J, **Mauer M**, Burlina A, **Eng C, Hopkin RJ**, Laney D, Linhart A, Waldek S, Wallace E, Weidemann F, **Wilcox WR**. *Fabry disease revisited: Management and treatment recommendations for adult patients.* Mol Genet Metab. 2018 Apr;123(4):416-427. doi: 10.1016/j.ymgme.2018.02.014. Epub 2018 Feb 28. (p. 419).

approach to patient care that reflects the genotype, gender, family history, phenotype, and specific clinical symptom severity of a given patient." *Id.*

180. These researchers still danced around the core issue of whether or not "low dose" Fabrazyme was safe or effective because they knew from the U.S. Fabry Registry data that a blanket dose adjustment was "**insane**" and based on "bullshit data."

181. Sanofi Genzyme explicitly blamed the FSWG for requiring Americans to take the "low dose" while Europeans were allowed to take the full dose. In an Fabrazyme Supply Update sent only to Europeans on October 3, 2011, it said that "in the USA, where no other approved treatment for Fabry disease is currently available, the FSWG (Fabry Stakeholders Working Group) recommended that no group of [American] Fabry patients should be designated to receive full dose, as this would require a significant further reduction in dose or no treatment at all for other US patients treated with Fabrazyme."

182. By 2016, Defendants knew that one of the risk factors for severe clinical Fabry disease was "low dose" but affirmatively decided not to report it.

183. In October of 2020, the Defendants changed tactics for concealing the effects of "low dose" Fabrazyme while emphasizing the beneficial effects of receiving an FDA approved dose that the on the "low dose" patients."[22]

184. Instead of excluding the patients that received "low doses" as they had before, the Defendants averaged the dose longitudinally so patients receiving "low dose" would be

[22] **Hopkin RJ,** Feldt-Rasmussen U, **Germain DP**, Jovanovic A, Martins AM, Nicholls K, Ortiz A, Politei J, Ponce E, Varas C, Weidemann F, Yang M, **Wilcox WR**. *Improvement of gastrointestinal symptoms in a significant proportion of male patients with classic Fabry disease treated with agalsidase beta: A Fabry Registry analysis stratified by phenotype.* Mol Genet Metab Rep. 2020 Oct 30;25:100670.

considered "nearly given" the recommended dosage of Fabrazyme.

185. Specifically, in a subsequent study on Fabry registry subjects, the inclusion criteria were "an average dose at or near the licensed dose of 1 mg/kg EOW [every other week] (range 0.9–1.1 mg/kg EOW)." It also states that "Registry data entered up to January 8th, 2019, w[as] analyzed," which includes the same patients that had been excluded from the prior studies.

186. Since significant time had passed since the shortage, the patients that once received "low doses" would now "nearly" receive a full dose of Fabrazyme since the dose is averaged over 10-15 years.

187. Averaging the Fabrazyme dosage when reporting data over a longitudinal study is misleading in two ways.

188. First, any adverse events observed on "low dose" are diluted over time.

189. Second, once a treatment benefit of full dose is identified, the study's statistical power is artificially magnified even though for part of the time, patients did not receive the FDA recommended dosage.

190. Consequently, the physician Defendants are continuing to actively conceal the effects of "low dose" on the Plaintiffs and all other Americans were required to take it for two and one-half years.

191. No one in the United States benefited from the mandated experimental use of "low dose" Fabrazyme.

CLASS ALLEGATIONS

192. Researching the effects of substituting an ineffective treatment for a disease and then monitoring the effects on patients follows a long line of infamous cases in U.S. history. Such cases share common actors, common facts, and common injuries, so they have been handled as a class.

193. Pursuant to Federal Rule of Civil Procedure 23, Plaintiff Masula, Plaintiffs herein, and all others similarly situated, request certification of this case for any U.S. citizen that is or was a research subject of the effects of "low dose" Fabrazyme ("the Class").

194. The requirements of Rule 23(a)(1) are satisfied. With respect to the torts of the Defendants against the Plaintiffs and the required medical monitoring, the proposed Class is so numerous that joinder of all members of the Class is impractical and the administration of the claims as set forth herein on behalf of the Class is more efficient and will benefit the parties and the Court.

195. The exact size of the Class and the identities of the individual members thereof are ascertainable through Defendants' records, including but not limited to the Fabry Registry.

196. The requirements of Rule 23(a)(2) are satisfied. With respect to the torts committed by the Defendants and the required medical monitoring, the questions of law and fact common to the Class predominate over the questions affecting only individual members of the Class, including the following:

a. Whether reduced dose Fabrazyme is ineffective to treat Fabry

disease;

b. Whether Defendants knew, or should have known, that reduced dose Fabrazyme was ineffective to treat Fabry disease;

c. Whether the reduced dose can cause an increased risk of future medical conditions, which require medical monitoring, thereby enforcing FSWG's promise to undertake a study of the effects of "low dose" Fabrazyme on Americans; and

d. Whether the Class is entitled to damages as a result of Defendants' conduct, including reimbursement for the costs of contaminated Fabrazyme, the costs of medical monitoring, the personal injuries suffered by recipients, conservatorship of the data unlawfully from the Plaintiffs, and punitive damages, and/or attorneys' fees and costs.

197. The requirements of Rule 23(a)(3) are satisfied. Plaintiff's claims as set forth herein are typical of the claims of the Class as they have all suffered similar harms, namely, financial loss, physical injury, and the need for future medical monitoring, and are based on the same legal theories related to the allegations of Defendants' actions and omissions.

198. Plaintiff and members of the Class were all research subjects during the relevant time period.

199. The requirements of Rule 23(a)(4) are satisfied. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class because her interests do not conflict with the interests of the individual members of the Class. Plaintiff will fairly, adequately, and vigorously represent and protect the interests of the members of the Class and has no antagonistic interest to the members of the Class. Plaintiff will retain competent and experienced counsel to represent herself and the members of the Class if the Class is certified.

200. The claims of Plaintiff and the Class are substantially identical, as explained above. The aggregate damages that may be awarded to members of the Class are likely to be

substantial, whereas the expense and burden of prosecuting such claims on an individual basis would be burdensome, economically infeasible, and procedurally impracticable. Certifying the Class will centralize these substantially identical claims in a single proceeding, which is the most manageable litigation method available to Plaintiff and the Class.

WHEREFORE, Plaintiffs demand judgment against Defendant, jointly and severally, in an amount in excess of $5,000,000.00, together with costs of suit and punitive damages as applicable. JURY TRIAL DEMANDED.

COUNTS

COUNT I: TORT OF FAILURE TO OBTAIN INFORMED CONSENT

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v.

UNIV. OF IOWA HOSPITALS AND CLINICS; ADEMOLA ABIOSE; COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; UNIV. OF WASHINGTON MEDICINE; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; UNIV. OF ALABAMA AT BIRMINGHAM MEDICINE; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

201. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

202. The tort of informed consent exists at common law in all states and is

foundational under Constitutional federal law's right to medical autonomy. See generally, *Cruzan by Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261 (1990) and *Id.* at 269. (This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment). *See also* 45 CFR §46.116 General Requirements for Informed Consent.[23]

[23] (a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

203. Due to the change in dose that the researchers had recommended, the researcher-subject relationship for the Plaintiffs and other Fabry Registry participants changed so substantively that a new informed consent was (and still is) required to collect further data on the subjects.

204. The physician Defendants did not disclose any risk, much less material risks, to taking low dose Fabrazyme.

205. The physician Defendants used coercive tactics, including cherry-picking research studies to present a positive result from using "low dose," failing to inform subjects how to obtain full doses

206. The physician Defendants also used coercive tactics by making it seem that it was "low dose" or nothing when Replagal was available as an alternative to "low dose."

207. In addition, the physician Defendants were coercive. They appealed to the entire U.S. Fabry community to accept "low doses," thus making it shameful to request a full dose even though it would be in their best interest.

208. One risk of taking "low dose" Fabrazyme is that the Fabry vascular globotriaosylceramide deposition will increase, thereby injuring the brain, kidney, heart, and nervous system.

209. A second risk of taking "low dose" Fabrazyme is antibody sensitization to the Fabrazyme itself, resulting in anaphylaxis when patients return to full dose.

210. A third risk is the acceleration of the Fabry disease process through unknown mechanisms, as reported by the European Medicines Agency.

211. The fourth risk of taking "low dose" includes the "residual effects" disclosed by

Defendants Warnock and Mauer.

212. These risks actually materialized in the Plaintiffs as evidenced by their decline in clinical status during the shortage and did not return to their original health when full doses were instituted two and one-half years later.

213. Plaintiffs would not have taken "low dose" Fabrazyme had they had that low dosing was "**insane**" and based on "bullshit data."

214. The physician Defendants further breached the duty of providing informed consent to the American Fabry Registry subjects by failing to act without consideration of age or vulnerability or abide by the Plaintiffs' prescribing physician's prescription for full dose, which led to the expected injuries of males having worse clinical outcomes than similarly dosed females, although all suffered worse clinical outcomes than if they had received full doses for the two and one-half years that the "low dose" effects were studied.

215. The physician Defendants also breached the duty of providing informed consent to the American Fabry Registry subjects by not submitting the change in protocol from being observational at 1mg/kg every other week to an experimental dose violating procedural protections against human experimentation, which would have protected the Plaintiffs from being offered a "low dose" in the first place.

216. In addition, the physician Defendants breached the duty of providing informed consent to the American Fabry Registry subjects by not providing a way for the Defendants to opt out of the experimental lose dose when their disease was increased. Thus the "low doses" were coerced by a mandate for Americans but not Europeans.

217. The physician Defendants also breached the duty of providing informed consent

to the American Fabry Registry subjects by not timely reporting that adverse events were increasing in the patients that were receiving "low dose" Fabrazyme.

218. The physician Defendants further breached the duty of providing informed consent by subsequently concealing the adverse effects of low dose despite such data being "essential" to determine the medical effect of "low dose" on Fabry patients.

219. Defendant entities monitored the physician Defendants but never enforced their policies against unethical human research in addition to vicarious liability attaching under the doctrine of *respondeat superior*.

220. Moreover, the entity Defendants provide medical care to a subset of Fabry Registrants and provide data to the Fabry Registry and are thus active participants in the research being conducted without informed consent.

221. The entity Defendants have also failed to report (and continue) to fail to report the research misconduct to federal and state authorities despite being under a duty to do so.

222. Both the entity and physician Defendants breached the duty of providing informed consent to the American Fabry Registry subjects by not providing full disclosure of the monies the Defendants had received and continued to receive from Sanofi Genzyme during the human experimentation on "low dose" Fabrazyme from 2009-2012.

223. The Defendants have continued in their misconduct through overt acts of statistical manipulation of data reported in 2016 and, most recently, in October of 2020.

224. In addition to the physical injuries and having to pay hundreds of thousands of dollars for a drug that the Defendants knew was medically worthless, the Plaintiffs have also suffered the indignity of being treated as less-than other Fabry disease patients.

225. The Plaintiffs did not and could not determine that "low dose" was utterly useless without the evidence discovered from the unsealing of the *Schubert* Complaint.

226. Physician Defendants knew that U.S. patients were under the mistaken impression that "low dose" Fabrazyme was clinically valuable in that "something would be better than nothing." Still, the Defendants failed to point this out even though they had a duty to speak.

227. The tort has continued because each time researchers access the Fabry Registry, a new dignitary injury occurs absent a obtaining new informed consent.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in the amount six-hundred thousand dollars ($600,000) per U.S. Fabry Registry victim per year that they received the "low dose" for a total of two billion one hundred and fifteen million dollars ($2,115,000,000), together costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT II: BREACH OF FIDUCIARY

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

UNIV. OF IOWA HOSPITALS AND CLINICS; ADEMOLA ABIOSE; COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; UNIV. OF

WASHINGTON MEDICINE; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; UNIV. OF ALABAMA AT BIRMINGHAM MEDICINE; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

228. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

229. The physician Defendants stood and still stand in an archetypal fiduciary role of researcher-human research subject special confidence and trust resulting from a position of superiority and influence acquired by virtue of participating in the FSWG.

230. The physician Defendants also created a position of a fiduciary by causing Plaintiffs to rely on "low doses" for treatment of Fabry Disease in the United States by recommending it in the first place even though there was no substantial evidence that it would work in lieu of full doses.

231. The physician Defendants induced this reliance by assuming an autonomous and coercive role in treating Fabry patients independent of the prescribing physician's judgment to give full doses.

232. The physician Defendants breached their fiduciary responsibility by placing the needs of the generic U.S. Fabry community above the interests and needs of individual Fabry patients.

233. The physician Defendants also breached their fiduciary responsibility of full disclosure by not telling anyone that alternative treatment, Replagal, was available through the FDA.

234. The physician Defendants breached their fiduciary responsibility by misleading

the Plaintiffs into believing that "something was better than nothing."

235. The duty was further breached by concealing (and continuing to conceal) the data proving "low dose" Fabrazyme was medically useless in treating the Plaintiffs and the other research subjects in the Fabry Registry. [24]

236. The physician Defendants' fiduciary duty has not ended because they still collect data on the Plaintiffs and most other American Fabry disease patients through the Fabry Registry.

237. The Defendants have continued in the misconduct through statistical manipulation of data in both 2016 and, most recently, in October of 2020.

238. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act with the honesty in addition to vicarious liability attaching under the doctrine of *respondeat superior*.

239. Moreover, the entity Defendants provide medical care to a subset of Fabry Registrants and provide data to the Fabry Registry and are thus continuing to be active participants in the research that was tortiously conducted and is still tortiously conducted on the U.S. Fabry patients.

240. The Plaintiffs did not and could not determine that "low dose" was completely useless without the evidence discovered from the unsealing of the *Schubert* Complaint.

241. Plaintiffs would not have taken "low dose" Fabrazyme had they had that low

[24] The last time the Supreme Court allowed an ineffective drug to be marketed under common law in the U.S. was in 1911 for "Dr. Johnson's Mild Combination Treatment for Cancer" because the seller did not mislead about the ingredients but only misled about the effectiveness of the drug for treating cancer. President Taft subsequently encouraged Congress to tighten the Food, Drugs and Cosmetics Acts to prevent such sales of ineffective drugs from happening again and the law was changed.

dosing was "**insane**" and based on "bullshit data" and would have stopped taking "low dose" Fabrazyme had they known.

242. Physician Defendants knew that U.S. patients were under the mistaken impression that "low dose" Fabrazyme was clinically valuable in that "something would be better than nothing," but Defendants knew otherwise and had undertaken a duty to speak as a continuing fiduciary to the patients that received "low dose" Fabrazyme.

243. The Plaintiffs continue to rely on the fiduciary responsibilities of the physician Defendants to report the adverse events, the lack of effectiveness, and the residual effects of receiving "low dose" Fabrazyme because the Plaintiffs do not have access to the data in the U.S. Fabry Registry.

244. The tort has continued because the research is ongoing. As such, a fiduciary must correct past misstatements and misimpressions as part of the continuation of the fiduciary relationship.

245. Thus, as a direct and proximate result of Defendants' conduct alleged herein, Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT III: (42 U.S.C. § 1981) Equal Protection under the Law

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO;

INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

UNIV. OF IOWA HOSPITALS AND CLINICS; ADEMOLA ABIOSE; COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; UNIV. OF WASHINGTON MEDICINE; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; UNIV. OF ALABAMA AT BIRMINGHAM MEDICINE; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

246. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

247. Physician Defendants and entity Defendants interfered with the Plaintiffs' fundamental state and federal constitutional right to medical autonomy.

248. Plaintiffs had an individualized doctor-patient contract with their treating physician with which the Defendants interfered.

249. The discriminatory conduct was for access to a drug in which the U.S. government held rights under the Bayh-Dole Act.

250. Defendants interfered with and countermanded U.S. Fabry Patients' right to choose the medical treatment that was individually best for them, which is especially egregious because the dosage they received was less than the government-approved FDA sanctioned dose.

251. The deprivation of the right to medical autonomy was specifically directed to a relatively small and vulnerable population that has a genetic mutation in their DNA.

252. The disabling of the right to medical autonomy was not equal. European Fabry

patients were given full dose as the cost of further reducing the doses to this vulnerable group of Americans.

253. Plaintiffs necessarily relied on the laws of the states and federal government to protect their right to medical autonomy.

254. "Low dose" treatment occurred at all the Defendants' facilities.

255. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

256. These violations of equal protection under the law were systematic and have continued over the years, including the most recent misconduct in October 2020 of statistically manipulating the Fabry Registry data when reporting it.

257. These violations continue in that the data is still being collected on U.S. Fabry Registry patients without informing them or their physicians of the effects of "low dose" so that the Plaintiffs can receive necessary medical care to treat "low dose" injuries.

258. The deprivation of the right to medial autonomy as a direct and proximate result of the Defendants' conduct alleged herein. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT IV: (42 U.S.C. § 1983)

Protection Of Rights from Those Acting Under Color of Law

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

UNIV. OF IOWA HOSPITALS AND CLINICS; ADEMOLA ABIOSE; COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; UNIV. OF WASHINGTON MEDICINE; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; UNIV. OF ALABAMA AT BIRMINGHAM MEDICINE; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

259. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

260. Physician Defendants and entity Defendants interfered with the Plaintiffs' fundamental state and federal constitutional rights to medical autonomy by interfering with and countermanding U.S. Fabry Patients' right to choose the individual medical treatment best for them. These acts are especially egregious because the dosage they received was a substitute for the FDA-approved dose known to be clinically effective.

261. The physician Defendants were acting under color of law because the unilateral substitution of the experimental dosage mandated across all 50 states in response to a drug shortage is a right reserved to public health authorities. The right to control public health for the

residents of the individual states is reserved to the sovereign States alone at common law and under the 10th Amendment.[25]

262. By usurping the role of public health authorities and the state-licensed physicians in treating the citizens of the 50 U.S. states, the Defendants acted both with color and force of law to defeat the state powers to address public health concerns within their state borders. The Defendants did not have any permission or authority from governmental bodies reduce the dose of Fabrazyme, a U.S. taxpayer funded invention.

263. The physician Defendants are also state-licensed individuals who acted as state-licensed authorities and used this power to coerce and mislead the American Fabry patients who received "low dose" Fabrazyme.

264. The FSWG and its members were not authorized by any state or the FDA to make substitutions for the FDA-approved doses of Fabrazyme during the shortage and were similarly prohibited from marketing or encouraging the use of such an unapproved drug under the 50 states' individual Pure Food and Drug acts and the federal Pure Food, Drug and Cosmetics Acts.

265. The deprivation of the right to medical autonomy was specifically directed to a relatively small and vulnerable population that has a genetic mutation in their DNA.

266. The disabling of the right to medical autonomy was not equal. No American group except for Fabry patients have ever been forced to use an experimental dose of an FDA approved drug. Even among those with Fabry disease, the Plaintiffs were treated unequally

[25] *See Jacobson v. Massachusetts*, 197 U.S. 11 (1905) generally and at 25 "[t]he State may invest local bodies called into existence for purposes of local administration with authority in some appropriate way to safeguard the public health and the public safety."

because some American patients and most European Fabry patients were allowed to obtain FDA approved doses on Fabrazyme. The Plaintiffs doses were decreased even further so that more Fabrazyme (a U.S. taxpayer funded invention) could be shipped overseas.

267. Since Fabrazyme is an invention funded and partially owned by the U.S. government, anyone receiving it must be given equal protection under the law.

268. These equal protections are vital so as not to remove the limitations on the government-granted monopoly powers under the Bayh-Dole act and under the Orphan Drug Act. For Fabrazyme, these protections are specifically designed to protect the intended beneficiaries of American Fabry patients, who constitute a rare disease population.

269. The deprivation of the right to medical autonomy was arbitrary and capricious because the patients' clinical need for full doses was not considered.

270. Plaintiffs necessarily rely on the laws of the states and federal government to protect their right to medical autonomy.

271. "Low dose" treatment has been administered at all of Defendant facilities.

272. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

273. These violations of equal protection under the law were systematic and have continued over the years, including the most recent misconduct in October 2020 of statistically manipulating the Fabry Registry data when reporting it.

274. These violations of equal protection continue in that the data is still being collected on U.S. Fabry Registry patients without revised consent or restitution and the treating physicians have not be informed of the injuries and risks of injury for the Plaintiffs receiving

"low dose."

275. The deprivation of the right to medial autonomy and informed consent is a direct and proximate result of the Defendants' alleged conduct.

276. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT V: (42 U.S.C. § 1985 (3)) Conspiracy to Deprive Rights from Citizens

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

UNIV. OF IOWA HOSPITALS AND CLINICS; ADEMOLA ABIOSE; COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; UNIV. OF WASHINGTON MEDICINE; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; UNIV. OF ALABAMA AT BIRMINGHAM MEDICINE; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

277. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

278. Physician Defendants and entity Defendants acted in concert to conspire to

remove the state and federal constitutional protections to medical autonomy by interfering with and countermanding U.S. Fabry Patients' right to choose the medical treatment that was individually best for them

279. The conduct is especially egregious because the dosage they received was less than the FDA approved dose of Fabrazyme and thus an untried and experimental dosage that had not been proven to be either safe or effective in the treatment of Fabry Disease.

280. Evidence of conspiracy exists in that the physician Defendants attended both the first and second FSWG meetings, except for Defendant Dr. Germain, who attended once. All of the physician Defendants sat on the U.S. Fabry Registry Board simultaneously during the shortage, and all of the Defendants have received (and continue to receive) monies from Sanofi Genzyme

281. The Defendants still work together to publish data on their victims while concealing the effects of "low dose" from the Plaintiffs.

282. These violations of equal protection and the right to medical autonomy under the law were systematic and have continued over the years, including the most recent misconduct in October 2020 of statistically manipulating reporting Fabry Registry data.

283. These violations also continue because the data is still being collected on U.S. Fabry Registry patients without revised informed consent or restitution.

284. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

285. "Low dose" treatment occurred at all of the entity Defendants' facilities.

286. The deprivation of the right to medial autonomy and informed consent is a direct

and proximate result of the Defendants' alleged conduct.

287. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT VI: (42 U.S.C. § 1986) Negligent Deprivation of Rights of Citizens

D.J.; TONI CORDOVA; JOHN CORTINA; GEORGE DEMKO; DONOVAN HELTON; MARY HELTON; SYDNEY JOHNSON; DAMON LAFORCE; MICHAEL MASULA; JAMES MATTHEWS; THOMAS OLSZEWSKI; THOMAS STANZIANO; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED

v.

UNIV. OF IOWA HOSPITALS AND CLINICS; ADEMOLA ABIOSE; COLUMBIA UNIV. MEDICAL CENTER; MARYAM BANIKAZEMI; CHILDREN'S MEMORIAL HOSPITAL; JOEL CHARROW; BAYLOR COLLEGE OF MEDICINE; CHRISTINE ENG; CINCINNATI CHILDREN'S HOSPITAL; ROBERT HOPKIN; UNIV. OF MINNESOTA; MICHAEL MAUER; DUKE UNIV. HEALTH CENTER; MANESH PATEL; UNIV. OF WASHINGTON MEDICINE; RONALD SCOTT; MASSACHUSETTS GENERAL HOSPITAL; KATHERINE SIMS; UNIV. OF ALABAMA AT BIRMINGHAM MEDICINE; DAVID WARNOCK; CEDARS-SINAI MEDICAL CENTER; WILLIAM WILCOX; UNIV. OF VERSAILLES; AND DOMINIQUE GERMAIN

288. Plaintiffs incorporate all preceding paragraphs and further alleges as follows:

289. Since the physician Defendants and entity Defendants acted in concert to conspire to remove the state and federal constitutional protections to medical autonomy, they were also obligated to act when they observed additional violations of protections under the law.

290. The tortious acts of the conspirators were both observed and facilitated by others.

291. Defendant entities monitored the physician Defendants but have never enforced their policies requiring researchers to act within the Federal law governing medical research.

292. "Low dose" treatment occurred at all of entity Defendants facilities.

293. Their failure to act has resulted in the continued systematic deprivation of medical autonomy and informed consent over the years, including the most recent misconduct in October 2020 of statistically manipulating the Fabry Registry data when reporting it.

294. The research and publication of data on the victims required numerous other individuals to act at the direction of the named Defendants.

295. These violations also continue because the data is still being collected on U.S. Fabry Registry patients without revised consent or restitution.

296. The deprivation of the right to medial autonomy and informed consent is a direct and proximate result of the Defendants' alleged conduct.

297. Plaintiffs suffered the harms alleged and are entitled to such relief.

WHEREFORE, Plaintiffs demand judgment, individually and on behalf of all others similarly situated, against Defendant in an amount in excess of $75,000.00, together with costs of suit and punitive damages. JURY TRIAL DEMANDED.

COUNT VII: VIRGINIA WRONGFUL DEATH (Code of Virginia §8.01-50) or in the alternative SURVIVAL ACTION CLAIMS (Code of Virginia §8.01-25)

EDDIE VIERS, individually and as administrator of THE ESTATE OF TERESA VIER as substituted for Teresa Viers; JEANNE WALLACE, individually and as administrator of THE ESTATE OF JOSEPH WALLACE as substituted for Joseph Wallace; WITH JAMES WALLACE; AND WITH SAMUEL WALLACE; INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED v. ALL DEFENDANTS

298. The preceding paragraphs are incorporated by reference as though set forth herein their entirety.

299. Eddie Viers, individually and as Administrator of the Estate of Teresa Viers, brings this action on behalf of the beneficiaries under and by virtue of the Wrongful Death Act, Code of Virginia §8.01-50, and the applicable rules of civil procedure and decisional law.

300. Jeanne Wallace, individually and as Administrator of the Estate of Joseph Wallace brings this action on behalf of the beneficiaries under and by virtue of the Wrongful Death Act Code of Virginia §8.01-50 and the applicable rules of civil procedure and decisional law.

301. As a result of the Defendants' acts and omissions, Teresa Viers and Joseph Wallace were caused grave injuries and death, resulting in the entitlement to damages to those individuals defined as beneficiaries under the Wrongful Death Act.

302. The named administrators claim all administrator's expenses recoverable under the Wrongful Death Act, including, but not limited to damages for hospital, medical, funeral, and burial expenses and all expenses of administration made necessary because of Teresa Viers' and Joseph Wallace's deaths.

303. The Wrongful Death Act beneficiaries of the Estate of Teresa Viers are Eddie Viers, spouse

304. The Wrongful Death Act beneficiaries of the Estate of Joseph Wallace are:

a. Jeanne Wallace, spouse;

b. James Wallace, son and

c. Samuel Wallace, son.

305. On behalf of wrongful death beneficiaries, the Administrators claim damage for monetary support that decedents would have provided to the beneficiaries during their lifetime, including, but not limited to the support provided or which could have been expected to have been provided to the beneficiaries.

306. On behalf of the beneficiaries, the Administrators claim damages for loss of companionship, comfort, society, guidance, solace, and protection by the decedents.

307. On behalf of the wrongful death beneficiaries, the Administrators claim damages for the full damages allowed under the Wrongful Death Act of Virginia and decisional law interpreting the Act.

WHEREFORE, Plaintiffs demand damages against Defendants in an amount in excess of $50,000.00, exclusive of pre-judgment interest, post-judgment interest and costs. JURY TRIAL DEMANDED

AND IN THE ALTERNATIVE--SURVIVAL ACTION[26]

308. On behalf of the Survival Action beneficiaries under Code of Virginia § 8.01-25, the Administrators claim all loss of income, retirement, and social security income as a result of the deaths of Teresa Viers and Joseph Wallace.

309. On behalf of the Survival Act beneficiaries, the Administrator claims damages for the pain, suffering and inconvenience endured by Teresa Viers and Joseph Wallace, including, but not limited to their physical pain and suffering and mental pain and suffering.

310. Plaintiffs claim the full measure of damages under the Survival Act.

[26] *See Centra Health, Inc. v. Mullins* 277 Va. 59, 79 (2009) explaining that both causes of action can be brought until proximate cause is determined, but election is not required earlier.

WHEREFORE, Plaintiffs demand damages against Defendant in an amount in excess of $50,000.00 under the Survival Act, exclusive of prejudgment interest, post- judgment interest and costs. JURY TRIAL DEMANDED

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a. An order for the immediate cessation of collection of data on U.S. Fabry patients until the National Institutes of Health can review the protocols for ClinicalTrials.gov Identifier: NCT00196742.

b. An order that a conservatorship be placed over these data so that patients can be re-consented and for those agreeing, the unrestricted publication of the de-identified full clinical results that have been obtained from "low- dosing" Americans with Fabrazyme in fulfillment of Defendants' promise to monitor "low dose" effects and to promote the advancement of medical science on Fabry disease;

c. Certification of this action or common issues herein as a class action;

d. A determination of common issues and claims in a unitary, consolidated, or class-wide trial pursuant to Fed. R. Civ. P. 23 and/or Fed. R. Civ. P 42;

e. An award of compensatory damages to each injured class member in an amount deemed appropriate by the trier of fact;

f. An award of punitive damages for acts and omissions of Defendant found to be willful and wanton, outrageous, and made with wickedness and reckless indifference to Plaintiffs' lives, health and interests;

g. An award of compensatory, equitable and/or restitution damages according to proof and for all applicable damages, remedies, and relief under applicable federal and state statutes including medical monitoring;

h. An award of costs of suit; and

i. Any other and further legal and/or equitable relief to which Plaintiffs might be entitled at law or which this Court deems proper.

JURY TRIAL DEMANDED

For the Plaintiffs,

/s/ C. Allen Black, Jr.

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